JUN 12 2012 K120769
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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

| | |
|---|---|
| **Applicant:** | Storz Medical AG<br>2151 E. Grand Avenue<br>El Segundo, CA 90245 |
| **Contact:** | Leigh Spotten<br>Regulatory Affairs Manager<br>Phone: (424) 218-8738 |
| **Device Identification:** | Trade Name:<br>Storz Modulith SLK<br>Common Name:<br>Extracorporeal Shock-Wave Lithotriptor<br>Classification Name:<br>Lithotriptor, Extracorporeal Shock-Wave, Urological |
| **Date of Preparation** | June 7, 2012 |
| **Regulation:** | 21 CFR 876.5990 |
| **Product Code:** | LNS |
| **Predicate Devices:** | Storz Modulith SLK<br>(K011700, cleared 08/16/2002) |
| **Indication:** | The STORZ MEDICAL Lithotripter Model Modulith SLK is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter. |
| **Device Description:** | The Storz Modulith SLK is a modification of the previously cleared Storz Modulith SLK, K011700. The device consists of a Shockwave Generator, an operator interface/touch panel, and a coupling cushion. Shock waves are generated when a rapid current pulse changes the diameter of a cylindrical shaped body. The shock waves are focused by a parabolic reflector. A water circuit is used to for generating the required coupling pressure.<br><br>The Modulith SLK has been modified to include an integrated patient table, the Lithotrack optical coupling C-Arm alignment mechanism was replaced with the crosshair manual aiming mechanism used in the Modulith SLX-F2 device (K072788), and an updated user interface that includes patient table movement control. It is intended to be used properly by trained and qualified medical personnel for use in noninvasive fragmentation of urinary calculi in the kidney and the upper ureter. The modifications incorporated do not alter the intended use or the fundamental technology and also does not raise any issues of safety and effectiveness. |

**Technological Characteristics:**

| Device Name | Storz Modulith SLK (Subject Device) | Storz Modulith SLK (Predicate Device ) |
|---|---|---|
| 510(k) Number | Not yet assigned | K011700 |
| Intended Use | non-invasive fragmentation of urinary calculi in the kidney and upper ureter | identical |
| Transport concept | Wheel based concept | identical |
| Penetration depth | 150 mm | identical |
| Diameter of therapy source | 178 mm | identical |
| Energy levels | 1 to 9 (increments of 1) and 10 to 90 (increments of 5) | identical |
| Positive peak pressure | 17 – 92 MPa | identical |
| Axial dimension of the -6dB focal volume | 88 – 54 mm | identical |
| Lateral dimension of the-6bD focal volume | 4.2 – 10 mm | identical |
| Shockwave source positioning Principle | Movable arm for under and over the table position of the therapy head. | Freely articulated arm for over table positioning of the therapy head. |
| Type | PCCU (Pulse current and charging unit) | PCCU (Pulse current and charging unit) |
| High voltage switch | Thyristor | Thyratron |
| X-Ray Localization Type | External C-arm | identical |
| Alignment control of C-arm | Manual aiming process in central opening of therapy head | Optical coupling (Lithotrack) |
| Ultrasound Localization Type | External ultrasound device | identical |
| Localization principle | In-line (in the central opening of the coil) | identical |
| Transducer | Aloka UST-9102U-3.5 | identical |
| Movements of transducer | Rotation manual, lift motorized | identical |
| Patient table | Integrated table | Separate table (e.g. TRUMPF MARS endouro) |
| Max. Patient weight | 225 kg for integrated table | 225 kg for Trumpf MARS endouro |
| Control panel lithotripsy | Touch screen display. Shock wave parameters and controls are all time visible. | Foil keyboard with dot-matrix character display (shock wave counter or menu display) and 7 segment displays (for |

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|---|---|---|
| | | energy level, frequency, cushion level) |
| Table controls | Integrated in touch screen of the MODULITH SLK | Separated control panel |
| Emergency halt | Emergency halt for table motions, shock wave release and cushion inflation | Not available |

The shock wave characteristics reported below were measured according to the guideline described in the consensus standard IEC 61846 "Ultrasonics- Pressure pulse lithotripters- Characteristics of fields" (1998). A glass fiber hydrophone was used in the measurements. The results are found similar to the predicate device characteristics

| Parameter | Min | Typical | Max |
|---|---|---|---|
| Peak-positive acoustic pressure (MPa) | 17 | 44 | 92 |
| Peak-negative acoustic pressure (MPa) | 9 | 16 | 20 |
| Rise time (ns) | 700 | 200 | 40 |
| Compressional pulse duration (ns) | 1200 | 670 | 250 |
| Maximum focal width (mm) | 10 | 6.3 | 4.2 |
| Orthogonal focal width (mm) | 10 | 6.3 | 4.2 |
| Focal extent (mm) | 88 | 62 | 54 |
| Focal volume ($mm^3$) | 4.6 | 1.3 | 0.5 |
| Distance between the focus and target location (mm) | $\leq 2.5$ | $\leq 2.5$ | $\leq 2.5$ |
| Derived focal acoustic pulse energy (mJ) | 20 | 23 | 23 |
| Derived acoustic pulse energy (mJ) | 5 | 16 | 30 |

**Non-Clinical Performance Data:** The STORZ MEDICAL Lithotripter Model Modulith SLK has undergone bench testing for its functions and performance, including verification of aiming accuracy, peak positive pressure and energy level of the shockwaves, software validation. Safety testing has been performed per FDA recognized standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-36 and IEC61846.

**Conclusion:** The STORZ MEDICAL Lithotripter Model Modulith SLK is substantially equivalent to its predicate devices and the non-clinical testing demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Ms. Leigh Spotten
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JUN 12 2012

Re: K120769
Trade/Device Name: Modulith SLK
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: May 11, 2012
Received: May 14, 2012

Dear Ms. Spotten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120769

**Indication for use**

510(k) Number (if known): ~~Not assigned yet~~ K120769

**Device Name:** Modulith SLK

**Indications for use:** The STORZ MEDICAL Lithotripter Model Modulith SLK is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

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| Prescription Use ✓ (21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

12 June 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120769